


# **EXHIBIT 33**

		<b>UNITED STATES DEPARTMENT OF COMMERCE</b> <b>Patent and Trademark Office</b>	
		Address: <b>COMMISSIONER OF PATENTS AND TRADEMARKS</b> Washington, D.C. 20231	
<b>CONTROL NUMBER</b>	<b>FILING DATE</b>	<b>PATENT UNDER REEXAMINATION</b>	<b>ATTORNEY DOCKET NO.</b>
08/05/2007	12/11/98	5464632	P1047/20006
		<b>EXAMINER</b> BENSTON JR, W	
		<b>ART UNIT</b>	<b>PAPER NUMBER</b>
DATE MAILED: 1/11/99			

**OFFICE ACTION IN REEXAMINATION**

☒ Responsive to the communication(s) filed on 4/23/99. ☐ This action is made FINAL.

A shortened statutory period for response to this action is set to expire 2 month(s) from the date of this letter. Failure to respond within the period for response will cause termination of the proceeding and issuance of a reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

**PART I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.      | 3. <input type="checkbox"/> Notice of Informal Patent Drawing, PTO-948. |
| 2. <input checked="" type="checkbox"/> Information Disclosure Citation, PTO-1449. | 4. <input type="checkbox"/> _____                                       |

**PART II SUMMARY OF ACTION:**

- 1a. ☒ Claims 1-6 are subject to reexamination.
- 1b. ☐ Claims \_\_\_\_\_ are not subject to reexamination.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are confirmed.
4. ☒ Claims 1-6 are patentable.
5. ☐ Claims \_\_\_\_\_ are rejected.
6. ☐ Claims \_\_\_\_\_ are objected to.
7. ☐ The formal drawings filed on \_\_\_\_\_ are acceptable.
8. ☐ The drawing correction request filed on \_\_\_\_\_ is ☐ approved, ☐ disapproved.
9. ☒ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received, ☐ not been received, ☒ been filed in Serial No. 08/346,324 filed on 11/29/94.
10. ☐ Since the proceeding appears to be in condition for issuance of a reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 435 O.G. 213.
11. ☐ Other

cc: Requester

PTOL-466 (2-90)

TAKZ0001260

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## DETAILED ACTION

### *Reexamination*

Receipt is acknowledged of response to order granting request or reexamination filed on 4/23/99 .

The amendment dated 12/31/98 has been entered and the amendment raises a substantial new question of patentability .

### *Claim Rejections - 35 U.S.C. § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is lack of descriptive support in the patent for the following amended material .

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1. " Free of acids and any of any substance which develops a high viscosity in contact with water " .

2. " In the mouth in the absence of any chewing action " .

In accordance with MPEP 714.02 , pp 700-111 and 700-112 , ( Rev .2, July 1996 ) applicants should specifically point out support for any amendments made to the disclosure .

The following is a quotation of the second paragraph of 35 U.S.C. 112:

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following enumerated reasons apply :

I. The expression " type " in claim 4 is indefinite .

II. Claim 6 lacks antecedent basis as claim 1 amended the expression by deleting " uncoated micro granules " .

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*Claim Rejections - 35 U.S.C. § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by SPARKS et al. , U.S. Patent 4,940, 588 ( '588 ).

See example 20 at col.20 where the patent discloses that the tablets disintegrate rapidly in the mouth and do not need to be chewed . The disintegration time is less than 30 seconds which reads on the “ disintegration occurring in the mouth in less than 60 seconds “ . Acetaminophen reads on the claimed “ active ingredient “ , cross-povidone reads on the claimed disintegrating agent or reticulated PVP , microcrystalline reads on the claimed swelling agent . The same compound is also claimed in the reexam patent . The expression “ pharmanones “ reads on the claimed “ micro crystals or micro granules “ . The reexam patent does not define the particle size of the “ micro crystals or micro granules ” and as such it is the examiners position that the particle size

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disclosed in the patent at col.3 , lines 1-2 reads on both " micro crystals and micro granules " absence of competent documentation to the contrary . See the paragraph bridging cols 2-3 which reads on the coating of the " micro crystals or micro granules " . See col.6 , lines 26-36 where the particles are coated . See also col.5 , lines 40-60 .

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Rotman U.S. Patent 4,710, 384 ('384) .

See col.5 , experiment 1 , the disintegration is 5-10 seconds in the stimulated fluid which reads on the claim " without water " . See col.3 , lines 60 et seq for coating and the additives

7.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **J.VENKAT** whose telephone number is (703) 308-2439. The examiner can normally be reached on **MON-FRI from 9:30AM to 5:00PM**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **THURMAN K.PAGE**, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
J. VENKAT PH.D

PRIMARY EXAMINER  
ART UNIT 1615